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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,759

09/08/2003

David Lewis

48924-01030

1172

34013 7590 03/16/2007  
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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/657,759

Applicant(s)

LEWIS ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/22/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6-17,19-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-17,19-21 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/06 has been entered.

Receipt is acknowledged of amendments and Remarks filed on 12/22/06. Claims 1, 17 and 21 are amended, claims 2-5, 18, 22 and 23 are cancelled and claims 24-26 are added. Accordingly, claims **1, 6-17, 19-21, 24-26** are pending and under examination.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 6-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Lasserre et al (6,296,156).**

Wu teaches a medicinal aerosol steroid formulation product with enhanced stability. The steroid is a 20-ketosteroid having an OH group at the C-17 or C-21 position and the aerosol container has a non-metal interior surface which has been

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found to reduce chemical degradation of such steroids (see abstract). Wu also discloses that steroids, especially 20-ketosteroids, are subject to enhanced chemical degradation, when stored in contact with a metal container (particularly the metal oxide e.g.,  $Al_2O_3$  layer that forms on the interior surface of the container) (see page 3). The preferred 20-ketosteroids include budesonide, triamcinolone acetonide, dexamethasone and betamethasone. The most preferred type of container is a conventional aluminum (or aluminum alloy) aerosol canister, the interior surface of which is coated with an inert material, such as spray-coated, baked epoxy-phenolic lacquer. The internal surfaces of metal valve components in contact with the formulation are similarly coated with an inert material. Another preferred coating for the inside of the container is perfluoroethylenepropylene (FEP). The coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier and the inside and outside of the valve stem (see page 4). Wu lacks specific disclosure on the rolled neck canister.

Lasserre et al teaches a mounting device for mounting a valve on a container and a dispenser containing a product under pressure fitted with such a mounting device. The inner surface of the cup which comes in contact with the product is coated with a lacquer or some other inert thermoplastic layer (col. 1, lines 63-65). The container containing a product, particularly a liquid, placed under pressure by a conventional propellant, to be dispensed by actuation of the dispensing valve. The open end of the container is formed by a neck, the said neck having a profile capable of engaging with a

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portion formed on the said external first mounting means. The neck of the container may be rolled outwards with respect to the central axis of the container or alternatively may be rolled inwards with respect to the axis of the container. The neck of the container has an edge bent towards the central axis of the container (col. 4, lines 1-34). The container may be a one-piece aluminum can. The cup is made of plastic, such as polyacetal (col. 4, lines 63-67).

With regards to limitations of claims 6-7, wherein the valve is washed before crimping of the valve upon the canister, it is noted that such limitation is 1) a process step and typically process steps in a product claim are not given patentable weight. 2) not patentably distinguishable from prior art because ethanol, is known to be used for sterilization and also washing the valve with ethanol does not alter the set up of the device and does not affect the function of the device.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation, to have looked in the art for a more specific device with rolled neck to use with the said formulations, as taught by Lasserre et al with a reasonable expectations of successfully preparing, storing and delivering a stable steroid formulation. In other words a combination of the references would have led one of ordinary skilled in the art to the invention as claimed.

**Claims 17, 19-21 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Abplanalp et al (6,668,439).**

Wu et al, discussed above, teaches a metered dose inhaler device with a non-metal interior surface which has been found to reduce chemical degradation of formulations such as those comprising steroids. The device is said to be suitable for the storage and delivery of a stable solution formulation comprising a steroid. Wu et al, however, lacks disclosure on specific steps and the rolled neck.

Abplanalp et al discloses an apparatus for forming a double-segment overlapping gasket material for the mounting cup of an aerosol container comprising a punch mounted on a reciprocating ram having a central opening for the body of the mounting cup and a nose portion adapted to extend within the channel portion of the mounting cup (see abstract and col. 3, lines 22-31).

Abplanalp et al also discloses that the dispensing valve, crimped to a mounting cup having a sealing gasket, is normally mounted in a top opening of the container, which opening is defined by a component commonly referred to as the "bead" of the container opening. The mounting cup includes a central pedestal portion for crimping the dispensing valve, a profile portion extending outward from the pedestal portion, which profile portion merges into an upwardly extending body portion, the body portion emerging into a channel portion terminating in a skirt portion (col. 1, lines 31-43 and col. 7, lines 8-27).

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It is also disclosed that various types of sealing gaskets are known in the art. One common type of gasket comprises a conventional flat rubber gasket that is placed inside the channel of the mounting cup (col. 1, lines 53-65). The preferred form of the mounting cup, the fold-over sleeve gasket is an ultra low density polyethylene with an added thermoplastic elastomer (col. 4, lines 6-8).

Abplanalp et al teaches that valve assembly includes a mounting gasket and an upper rolled rim or bead that extends around opening. Folded-over gasket is disposed between bead and the under surface of channel (col. 5, lines 41-55).

With regards to limitations of claims 19 and 21, wherein the valve is washed before crimping of the valve upon the canister, it is noted that such limitation is not patentably distinguishable from prior art because ethanol, is known to be used for sterilization and also washing the valve with ethanol does not alter the set up of the device and does not affect the function of the device.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation stored and delivered by a suitable metered dose inhaler device, to have looked in the art for a more specific device with rolled neck to use with the said formulations, and for specific steps of mounting the cap and the gasket as taught by Abplanalp et al with a reasonable expectations of successfully preparing, storing and delivering a stable steroid

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formulation. In other words a combination of the references would have led one of ordinary skilled in the art to the invention as claimed.

### ***Response to Arguments***

Applicant's arguments filed 12/22/06 have been fully considered but they are not persuasive.

Applicant's main argument is that Wu and Lasserre are solving the problem of chemical stability of the formulation differently than the instant invention is. This is not persuasive. Firstly claims 1-16 are drawn to a product comprising a solution formulation product. It has been shown that the limitations pertaining to the product have been met by the cited prior art. Wu is clearly teaching the formulation and a canister with a gasket to prevent contact of the formulation with metal component (see page 6, lines 20-26).

Secondly, when Wu teaches that formulation should be kept away from the metal surfaces of the canister, it includes the edges of the neck too. Thus the combined references teach a method of providing a stable formulation. Lasserre et al teaches a similar device which has rolled rim. One of ordinary skill in the art would have been motivated to design the device with rolled neck to insure no contact between solution and the metal edges of the canister or its parts.

Applicant argues that Wu is solving the stability of the solution by coating the inside of the canister. This is correct but not persuasive, because the instant claims also require part or all of the internal surfaces be coated by inert material. Also the figures in the Wu et al reference show that the neck is rolled away and that the gasket keeps the



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formulation inside the canister and away from any contact with the metal part. This is exactly what the instant Application is claiming.

Applicant argues that Lasserre does not address the problem related to stability of the solution. Additionally it is argued that Lasserre teaches a spring-like connection for mounting a valve on a container where the spring is formed by bending the edge of the canister to form a rolled or bent neck. Applicant then concludes that Lasserre can not be combined with Wu. This is not persuasive because the steps related to the process claims are not given patentable weight in a product claim. It has been shown that a combination of Wu and Lasserre meet all the limitations of the product claims 1 and 6-16. A new rejection combining Wu and Abplanalp is addressing the steps of the process claims.


All pending claims are considered obvious over the cited prior art. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mina Haghghatian  
Patent Examiner  
March 14, 2007